

REMARKS

Claims 1-4, 8-10 and 12-50 are pending. In view of the following remarks, Applicant submits that pending claims 1-4, 8-10, and 12-50 are in condition for allowance.

Rejections Under 35 U.S.C. § 103(a)

A. Claims 1-4, 8-10, 12-31 and 48-50 over Inga in view of Ohkubo

Claims 1-5, 13-31 and 48-50 have again been rejected as allegedly obvious over U.S. Patent No. 5,384,643 (hereinafter "Inga") in view of U.S. Patent No. 6,449,502 (hereinafter "Ohkubo"). (Final Office Action, paragraphs 3-24). In response to Applicants' arguments that there is no motivation within the references to combine them as set forth in the Office Action, the Examiner again asserts that Inga describes a method of providing a digitized X-ray image; transmitting the image and analyzing data at a remote computer. (Final Office Action, paragraph 45, citing Background of Inga). Furthermore, the Office asserts that, although Inga does not disclose the type of information to be obtained from the image, this reference discloses that patient condition can be assessed and a therapy recommended. *Id.* Ohkubo is again cited for teaching analysis of radiation images to determine bone density. (Final Office Action, paragraph). Thus, the Examiner's position remains that:

[M]edical practitioners would immediately recognize the benefit of the teachings of Inga et al. and Ohkubo to devise a system where radiation images are assessed for a particular medical assessment of the patient, such as deriving quantitative information of bone from a radiation image at a remote location. (Final Office Action, paragraph 49).

Applicants traverse the rejection.

The Examiner's statement that medical practitioners would "immediately recognize the benefit" of combining Inga and Ohkubo is legally and factually inaccurate.

Legally, in order to establish a *prima facie* showing of obviousness, the onus remains on the Office to point to teachings or suggestions within the references themselves that would lead one of skill in the art to combine them as cited. *See, e.g., In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993), emphasis added. The Office cannot simply state, as it has done in this case, that medical practitioners would immediately recognize the benefit of combining Inga and

Ohkubo without providing supporting evidence or documentation. *See, e.g., In re Lee*, 61 USPQ2d 1430 (Fed. Cir. 2002), affirming that purported common knowledge and common sense are not the specialized knowledge and expertise necessary to establish a motivation to arrive at the claimed invention. Here, there is nothing in the references that would lead one to the methods as claimed.

Factually, it is clear that Inga is not concerned with transmission of bone-containing images for quantitative analysis and that Ohkubo is not concerned with transmission of any images whatsoever.

For its part, nowhere does Inga teach or suggest that the digitized and transmitted medical images must contain bone, as claimed. Furthermore, Inga is entirely unconcerned with deriving quantitative information about bone from any images, as claimed. Rather, the only "information" that Inga suggests can be derived from transmitted images is information previously derived by a radiologist (prior to transmission) or a rapid, qualitative, visual assessment during examination:

Typically, the physician examines the patient in his office **after** the radiographic studies have been made in a hospital or diagnostic facility. These films and the information contained therein are often unavailable at the time of examination. Thus, there is a need for remote access to these image data for **rapid** patient assessment and therapy recommendation. Inga, col. 1, lines 26-32, emphasis added.

Inga clearly teaches that any detailed information is derived by a radiologist prior to digitization and transmission, who then prepares a report:

FILM PREPARATION: The film(s) is developed to create a visible image with OCR readable patient identification information superimposed thereon.

FILM INTREPRETATION: Commonly, a radiologist drafts an opinion letter for the film(s). This document preferably includes an optical character reader, or OCR, readable patient identification label or standard marking area. (Inga, col. 3, lines 61-66).

Simply put, Inga does not teach or suggest that images containing bone could be transmitted so that quantitative information on bone can be gained after transmission, as claimed. Inga is silent as to deriving quantitative entirely and, at best, indicates that any detailed analysis must be done prior to transmission. Pre-transmission analysis is completely contrary to the claimed methods. There is nothing in Inga that would lead a medical practitioner to the

conclusion that a physician on the receiving end of the transmitted image would be able to (or in any way motivated to) analyze the transmitted image to obtain quantitative information regarding bone. Thus, Inga does not teach or suggest transmission of bone-containing x-rays so that the images can be quantitatively analyzed.

For the reasons of record, Ohkubo fails to supply what is missing from Inga. Ohkubo is completely silent as to digitizing x-ray images including bone or transmitting these images, as claimed. There is nothing in this reference that would motivate the medical practitioner to apply the methods to an x-ray image that had been digitized and transmitted to a remote location. Indeed, at best, combining Ohkubo and Inga would motivate the medical practitioner to have a radiologist analyze images as suggested by Ohkubo prior to transmission and then to transmit their report to the attending physician. A medical practitioner would have absolutely no reason to perform Ohkubo's analysis on transmitted images, particularly in view of the fact that Inga stresses transmission is strictly for the purpose of **rapid, in-office** examinations and assessments.

The fact remains that a *prima facie* case of obviousness cannot be established by picking and choosing individual elements from unrelated disclosures and simply asserting that a medical practitioner would "immediately recognize" were known and that the motivation to combine somehow derives from unrelated disclosures of these elements. Should the Examiner be relying on facts within her personal knowledge in asserting that the claimed methods are obvious over disclosures which fail to suggest the elements as claimed or in the combination as claimed, Applicants request, pursuant to 37 C.F.R. § 1.104(d)(2), that the data relied upon be stated more specifically and supported by an affidavit from the Examiner. *See, also* MPEP 2144.03.

B. Claims 32-45 and 47 over Chiabrera

Claims 32-45 and 47 are again rejected as allegedly obvious U.S. Patent No. 5,917,877 (hereinafter "Chiabrera"). (Final Office Action, paragraphs 25-43). The Final Office Action states, in part:

Chiabrera et al. teach that a calibration phantom can comprise a wedge construction wherein differing heights represent varying thicknesses thereby allowing the distinct identification of wedge attenuating characteristics (column 3, lines 65 through column 4, line 3). Based on the teachings of the construction of the Chiabrera et al. phantom, Examiner concludes that it would have been obvious to modify the calibration phantom such that it incorporated a marker in a known

density area of the phantom. One would have been motivated to make such a modification so that the marker serves as a positioning indicator for the phantom as well as an indicator for the attenuation of attributes of the phantom at the indicated position. Final Office Action, paragraph 50.

As with the rejections based on Inga discussed above, Applicants traverse the rejection because a *prima facie* case of obviousness cannot be established.

The Office admits that Chiabrera does not teach that a marker should be placed in a calibration phantom in an area of known density. (Final Office Action, paragraph 50). Nonetheless, the Office asserts, without pointing to particular passages or Figures as required, that Chiabrera somehow would have motivated one of skill in the art to arrive at the claimed devices, apparently because a wedge shape structure is somehow tantamount to a marker positioned in an area of known density. (Final Office Action, paragraph 50).

The fact that Chiabrera's calibration phantoms are wedge-shaped in no way means that they suggest use of a marker positioned in any area of known density as claimed. In fact, with regard to the importance of the marker and its placement, Applicants direct the Examiner's attention to page 27, lines 3-9 of their specification, which summarizes the problem with existing calibration phantoms and the claimed solution:

Whatever the overall shape of the calibration phantom, it is preferred that at least one marker be present at a known density in the phantom. Presently, areas of the calibration phantom will often fail to appear on x-ray images. This is particularly true of areas at the highest and lowest density levels. Thus, it is often difficult to determine what the density is of any particular area of the calibration phantom. The present invention solves this problem by ensuring that at least one geometric shape is including in the calibration phantom at a position of known density.

There is nothing in Chiabrera that suggests use of markers as claimed, let alone any indication of recognition of the problem solved by using such markers. This reference, like the art as a whole, assumes that placement alongside the bone is sufficient to ensure accuracy and provides no motivation or suggestion to place a marker at a position of known density within the calibration phantom. *See, e.g.*, Chiabrera, col. 6, lines 41-44 and claims.

Thus, because there is no motivation, suggestion or reason given in Chiabrera to place the calibration phantom in an area of known density, Applicants can only conclude that the rejection

is improperly based on hindsight reconstruction. Accordingly, withdrawal of this rejection is respectfully requested.

C. Claim 46 over Chiabrera in view of Inga

Claim 46 stands rejected as allegedly obvious over Chiabrera in view of Inga. (Final Office Action, paragraphs 41-44). The Final Office Action alleges, "it would have been obvious to modify the method of Chiabrera such that it incorporated the step of comparing performed in a network environment. One would have been motivated to make such a modification so that analysis could be accentuated by the ability to access several image and patient data from an archive source as taught by Inga et al. (Abstract, column 3, lines 17-45)." (Final Office Action, paragraph 44).

Claim 46 depends ultimately from claim 32. As such, the method of claim 46 requires the use of an assembly in which the calibration phantom is positioned in an area of known density. For the reasons of record and those detailed above, both the art as a whole and Chiabrera in particular fail to teach or suggest placement of a calibration phantom in any area of known density. Similarly, for the reasons of record and detailed above, Inga provides no motivation to obtain quantitative information from images after digitizing and transmitting the images. Accordingly, there no motivation in and no combination of Chiabrera and Inga that would reasonably lead one of skill in the art to the method of claim 46.

CONCLUSION

Applicant submits that the claims are in condition for allowance and request early notification to that effect. If the Examiner has any further issues or wishes to discuss any of the foregoing, she is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

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By: _____



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